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Substitute for form 1449A-PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 1 of 1

**Complete if Known**

Application Number	10/22,664
Int'l Filing Date	31 July 2003
First Named Inventor	Heinz-Josef LENZ
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	US7000732001

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number – Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/CM/	1	US-5,705,336	01-06-98	Reed et al.	
↓	2	US-6,716,581 B2	04-06-04	Lenz et al.	
	3	US-2004/0067519 A1	04-08-04	Lenz et al.	
		US-			
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> – Number <sup>4</sup> – Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
/CM/	4	WO 01/36686 A2 & A3	05-25-01	University of Southern California		
↓	5	WO 01/75175 A2, R5 & A3	10-11-01	University of Southern California		
	6	WO 2004/011625 A2 & A3	02-05-04	University of Southern California		

Examiner's  
Signature

/Carla Myers/

Date  
Considered

10/30/2007

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Sheet 1 of 3

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Application Number	10/522,664
Int'l Filing Date	31 July 2003
First Named Inventor	Heinz-Josef LENZ
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	US7000732001

**NON PATENT LITERATURE DOCUMENTS**

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/CM/	1	ABDEL-RAHMAN, S. et al. "Polymorphisms in DNA Repair Gene XRCC1 Increases the Risk of Colorectal Cancer in Egypt" <i>Proceedings of the American Association for Cancer Research</i> (March 2000) 41:595, No. 3791	
	2	BOARD, P.G. et al. "Isolation of a cDNA clone and localization of the human glutathione S-transferase 3 genes to chromosome bands 11q13 and 12q13-14" <i>Ann. Hum. Genet.</i> (1989) 53:205-213	
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	4	DUELL, E.J. et al. "Polymorphisms in the DNA repair genes XRCC1 and ERCC2 and biomarkers of DNA damage in human blood mononuclear cells" <i>Carcinogenesis</i> (May 2000) 21(5):965-971	
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	6	EDLER, D. et al. "Thymidylate Synthase Expression: An Independent Prognostic Factor for Local Recurrence, Distant Metastasis, Disease-free and Overall Survival in Rectal Cancer" <i>Clinical Cancer Research</i> (April 2000) 6:1378-1384	
	7	HALPERN, J. "Maximally Selected Chi Square Statistics for Small Samples" <i>Biometrics</i> (December 1982) 38:1017-1023	
	8	HARRIES, L.W. et al. "Identification of genetic polymorphisms at the glutathione S-transferase Pi locus and association with susceptibility to bladder, testicular and prostate cancer" <i>Carcinogenesis</i> (1997) 18(4):641-644	
	9	HEIDELBERGER, C. et al. "Fluorinated Pyrimidines, A New Class of Tumour-Inhibitory Compounds" <i>Nature</i> (March 30, 1957) 179:663-666	
	10	HORIE, N. et al. "Functional Analysis and DNA Polymorphism of the Tandemly Repeated Sequences in the 5'-terminal Regulatory Region of the Human Gene for Thymidylate Synthase" <i>Cell Structure and Function</i> (1995) 20:191-197	
↓	11	HORIKOSHI, T. et al. "Quantitation of Thymidylate Synthase, Dihydrofolate Reductase, and DT-Diaphorase Gene Expression in Human Tumors Using the Polymerase Chain Reaction" <i>Cancer Res.</i> (Jan. 1, 1992) 52:108-116	

Examiner's  
Signature

/Carla Myers/

Date  
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10/30/2007

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Sheet 2 of 3

**Complete if Known**

Application Number	10/522,664
Int'l Filing Date	31 July 2003
First Named Inventor	Heinz-Josef LENZ
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	US7000732001

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/CM/	12	HOWIE, A.F. et al. "Glutathione S-transferase and glutathione peroxidase expression in normal and tumour human tissues" <i>Carcinogenesis</i> (1990) 11(3):451-458	
	13	HU, J.J. et al. "Genetic Polymorphism of DNA Repair in Human Prostate Cancer Risk" <i>Proceedings of the American Association for Cancer Research</i> (March 2000) 41:596, No. 3798	
	14	ISHIKAWA, Y. et al. "Dihydropyrimidine Dehydrogenase Activity and Messenger RNA Level May Be Related to the Antitumor Effect of 5-Fluorouracil on Human Tumor Xenografts in Nude Mice" <i>Clin. Cancer Res.</i> (April 1999) 5:883-889	
	15	LEICHMAN, C.G. et al. "Quantitation of Intratumoral Thymidylate Synthase Expression Predicts for Disseminated Colorectal Cancer Response and Resistance to Protracted-Infusion Fluorouracil and Weekly Leucovorin" <i>J. Clinical Oncology</i> (Oct. 1997) 15(10):3223-3229	
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	17	MILLER, R. and D. SIEGMUND "Maximally Selected Chi Square Statistics" <i>Biometrics</i> (Dec. 1982) 38:1011-1016	
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	19	NISHIMURA, T. et al. "Association between expression of glutathione-associated enzymes and response to platinum-based chemotherapy in head and neck cancer" <i>Chemico-Biological Interactions</i> (1998) 111-112:187-198	
	20	PETERS, W.H.M. et al. "Expression of Drug-Metabolizing Enzymes and P-170 Glycoprotein in Colorectal Carcinoma and Normal Mucosa" <i>Gastroenterology</i> (Aug. 1992) 103:448-455	
	21	SALONGA, D. et al. "Colorectal Tumors Responding to 5-Fluorouracil Have Low Gene Expression Levels of Dihydropyrimidine Dehydrogenase, Thymidylate Synthase, and Thymidine Phosphorylase" <i>Clin. Cancer Res.</i> (April 2000) 6:1322-1327	
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	23	STERN, M.C. et al. "DNA Repair Gene XRCC1 Polymorphisms, Smoking and Bladder Cancer Risk" <i>Proceedings of the American Association for Cancer Research</i> (March 2000) 41:592, No. 3771	
✓	24	SWEENEY, C. et al. "Association between Survival after Treatment for Breast Cancer and Glutathione S-Transferase P1 Ile <sup>105</sup> Val Polymorphism" <i>Cancer Res.</i> (Oct. 15, 2000) 60:5621-5624	

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Signature

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Date  
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10/30/2007

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(use as many sheets as necessary)*

Sheet	3	of	3
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**Complete if Known**

<b>Application Number</b>	<b>10/522,664</b>
<b>Int'l Filing Date</b>	<b>31 July 2003</b>
<b>First Named Inventor</b>	<b>Heinz-Josef LENZ</b>
<b>Art Unit</b>	<b>Not Yet Assigned</b>
<b>Examiner Name</b>	<b>Not Yet Assigned</b>
<b>Attorney Docket Number</b>	<b>US7000732001</b>

## NON PATENT LITERATURE DOCUMENTS

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**Examiner's  
Signature**

/Carla Myers/

Date  
Considered

10/30/2007

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO

**Date Submitted: January 11, 2006**

(use as many sheets as necessary)

**Complete if Known**

<b>Application Number</b>	10/522,664
<b>Filing Date</b>	July 31, 2003
<b>First Named Inventor</b>	Heinz-Josef Lenz
<b>Group Art Unit</b>	Not Yet Assigned
<b>Examiner Name</b>	Not Yet Assigned
<b>Attorney Docket Number</b>	064189-0604

Sheet	1	of	2
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[illegible][illegible]

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10/30/2007

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  Date Submitted: January 11, 2006 <i>(use as many sheets as necessary)</i>				Application Number	10/522,664
				Filing Date	July 31, 2003
				First Named Inventor	Heinz-Josef Lenz
				Group Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	064189-0604

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (If known)				
/CM/	3	WO	04/037852	A2	University of Medicine and Dentistry of New Jersey; University of Southern California	May 6, 2004		

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↓	5	LENZ, HEINZ-JOSEF et al. "A 6 base-pair deletion in the 3' UTR of the thymidylate synthase (TS) gene predicts TS mRNA expression in colorectal tumors: A possible candidate gene for colorectal cancer risk" <i>Proceedings of the American Association for Cancer Research Annual Meeting</i> (March 2002) 43:660		
	6	PARK, DAVID J. et al. "Thymidylate synthase gene polymorphism predicts response to capecitabine in advanced colorectal cancer" <i>International Journal of Colorectal Disease</i> (January 2002) 17(1):46-49		
	7	PULLARKAT, S. et al. "Thymidylate Synthase Gene Polymorphism Determines Response and Toxicity of 5-FU Chemotherapy" <i>Pharmacogenomics Journal</i> (2001) 1(1):65-70		
	8	SHIROTA, Y. et al. "ERCC1 and Thymidylate Synthase mRNA Levels Predict Survival for Colorectal Cancer Patients Receiving Combination Oxaliplatin and Fluorouracil Chemotherapy" <i>Journal of clinical Oncology</i> (December 1, 2001) 19(23):4298-4304		
	9	Ulrich et al. "Searching Expressed Sequence Tag Databases: Discovery and Confirmation of a Common Polymorphism in the Thymidylate Synthase Gene" <i>Cancer Epidemiology, Biomarkers &amp; Prevention</i> (2000) 9:1381-1385		
	10	Villafranca et al. "Polymorphisms of the Repeated sequences in the Enhancer Region of the Thymidylate Synthase Gene Promoter May Predict Downstaging After Preoperative Chemoradiation in Rectal Cancer" (2001) <i>Journal of Clinical Oncology</i> 19(6):1779-1786		
	11	European Search Report for EP 03 77 2163 dated October 4, 2005		

Examiner Signature	/Carla Myers/	Date Considered	10/30/2007
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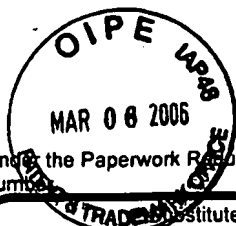


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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

<b>Application Number</b>	10/522,664
<b>Filing Date</b>	7/31/2003
<b>First Named Inventor</b>	Heinz-Josef Lenz
<b>Group Art Unit</b>	1634
<b>Examiner Name</b>	Carla J. Myers
<b>Attorney Docket Number</b>	064189-0604

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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INSTITUTE for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Date Submitted: March 3, 2006 (use as many sheets as necessary)		<b>Complete if Known</b>	
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/CM/	1	Kuniyasu et al. "Induction of angiogenesis by hyperplastic colonic mucosa adjacent to colon cancer" <i>American Journal of Pathology</i> (Nov. 2000) 157(5):1523-1535	
/CM/	2	Fox et al. "Angiogenesis in normal tissue adjacent to colon cancer" <i>Journal of Surgical Oncology</i> (Dec. 1998) 69(4):230-234	
/CM/	3	Liotta et al. "The microenvironment of the tumour-host interface" <i>Nature</i> (May 2001) 411(6835):375-379	
/CM/	4	European Search Report for EP 03772163.6 dated 2/3/06	
/CM/	5	Promega Catalog (1997) page 78	

Examiner Signature	/Carla Myers/	Date Considered	10/30/2007
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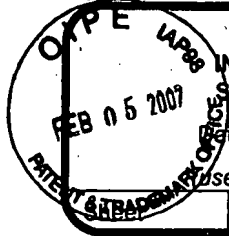
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Date Submitted: January 29, 2007

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1 of 1

## Complete if Known

Application Number	10/522,664
Filing Date	7/31/2003
First Named Inventor	Heinz-Josef Lenz
Art Unit	1634
Examiner Name	Carla J. Myers
Attorney Docket Number	064189-0604

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/CM/ ↓	1	5,985,561	11/16/1999	Kimberly et al.	
	2	2005/0064417	03/24/2005	Watier et al.	
	3	2006/0008825	01/12/2006	Levy et al.	

## UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS

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